



**WRP Asia Pacific Sdn Bhd**

FORMERLY KNOWN AS WEMBLEY RUBBER PRODUCTS (M) SDN BHD

147817V

**MAY 15 2000**

**510(k) SUMMARY**

*K 001280*

Lot 1, Jalan 3, Kawasan Perusahaan  
Bandar Baru Salak Tinggi,  
43900 Sepang,  
Selangor Darul Ehsan,  
**MALAYSIA**

TEL +60-3-846 1486

FAX +60-3-846 1485/1557

EML mktgwrp@ibm.net

URL www.wrpworld.com

**1.0 Submitter:**

Name: WRP Asia Pacific Sdn. Bhd.  
Address: Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak  
Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA  
Phone No.: +60 3 846 1486  
Fax No.: +60 3 846 1485

Date of Summary Prepared: March 28, 2000

**2.0 Contact Person:**

Name: Mr. Yue Wah, CHOW  
Phone No.: +60 3 846 1486  
Fax No.: +60 3 846 1485

**3.0 Name of the device:**

Trade Name: Comfit Powder Free Polymer Coated Latex Examination  
Glove, Non Sterile (Protein Content Labeling)  
Common Name: Examination Gloves  
Classification Name: Patient Examination Gloves (per 21 CFR 880.6250)

**4.0 Identification of The Legally Marketed Device:**

Class I patient examination gloves, 80LYY, powder free, that meets all the requirements of ASTM standard D 3578 – 99 and FDA 21 CFR 800.20.

**5.0 Description of The Device:**

The Powder Free Polymer Coated Latex Examination Glove, Non Sterile (Protein Content Labeling) meets all the requirements of ASTM standard D 3578 – 99 and FDA 21 CFR 800.20.

**6.0 Intended Use of the Device:**

The Powder Free Polymer Coated Latex Examination Glove, Non Sterile (Protein Content Labeling) are disposable devices intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

**7.0 Summary of The Technological Characteristics of The Device:**

The Powder Free Polymer Coated Latex Examination Glove, Non Sterile (Protein Content Labeling) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	ASTM D 3578 – 99	Meets
Physical Properties	ASTM D 3578 – 99	Meets
Freedom from pinholes	ASTM D 3578 – 99 FDA 21 CFR 800.20	Meets
Powder-Free	ASTM D 6124 – 97	< 2 mg/glove
Protein Level	ASTM D 5712 – 95	< 50 µg/g
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)

**8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data**

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

**9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data**

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.



## **10.0 Conclusion**

It can be concluded that the Comfit Powder Free Polymer Coated Latex Examination Glove, Non-Sterile (Protein Content Labeling) will perform according to the glove performance standards referenced in section 7 above and meet ASTM standards, and FDA requirements for waterleak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 15 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Yue Wah Chow  
Head of Department, QA/RA  
WRP Asia Pacific Sdn. Bhd.  
Lot 1, Jalan 3, Kawasan Perusahaan  
Bandar Baru Salak Tinggi  
43900 Sepang, Selangor Darul Ehsan  
MALAYSIA

Re: K001280  
Trade Name: Comfit Powder-Free Polymer Coated Latex  
Examination Glove, Non-Sterile with Protein Labeling  
Claim (50 Micrograms or Less)  
Regulatory Class: I  
Product Code: LYY  
Dated: April 18, 2000  
Received: April 21, 2000

Dear Mr. Chow:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your

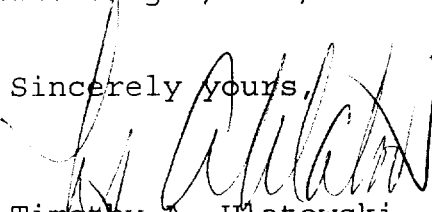
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premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

Applicant: WRP Asia Pacific Sdn Bhd

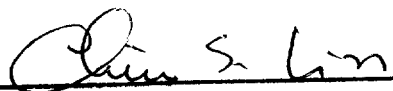
510(k) Number (if known): K001280

Device Name: COMFIT POWDER FREE POLYMER COATED LATEX  
EXAMINATION GLOVE, NON STERILE (PROTEIN  
CONTENT LABELING) 50 micrograms or less

### Indications For Use:

The Powder Free Polymer Coated Latex Examination Glove, Non Sterile (Protein Content Labeling) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K001280

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-The-Counter X